

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Farmer  
ASSIGNEE: Ganeden Biotech, Inc.  
SERIAL NUMBER: 09/647,695 EXAMINER: Davis, R.  
FILING DATE: April 6, 2001 ART UNIT: 1651  
FOR: METHODS FOR REDUCING CHOLESTEROL USING *BACILLUS COAGULANS*  
SPORES SYSTEMS AND COMPOSITIONS

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION OF SEAN FARMER UNDER 37 C.F.R §1.132

I, Sean Farmer, of Miami Beach, Florida, declare and state as follows:

1. I am a co-inventor of the invention claimed in the above-referenced application and am employed by the named assignee, Ganeden Biotechnology, Inc., San Diego, California.
2. I hold a B.A. degree in Evolutionary Biology from Princeton University and a M.S. degree in Microbiology from University of California Los Angeles. I have been involved in research relating to probiotics for at least 13 years.
3. I have read the Office Action mailed on November 3, 2003 and am familiar with the Examiner's grounds of rejection for obviousness.
4. I have performed, or have had performed under my supervision, studies evaluating the therapeutic effect of a probiotic composition containing *Bacillus coagulans* lactic acid-producing bacteria. The probiotic composition contains approximately 1 billion lyophilized vegetative cells of *Bacillus coagulans* bacteria and inert ingredients. The strain of *Bacillus coagulans* bacteria used in the probiotic composition is a strain of *Bacillus coagulans Hammer* (identified as ATCC No. 31284), which is disclosed at page 8, line 14 of the specification. The

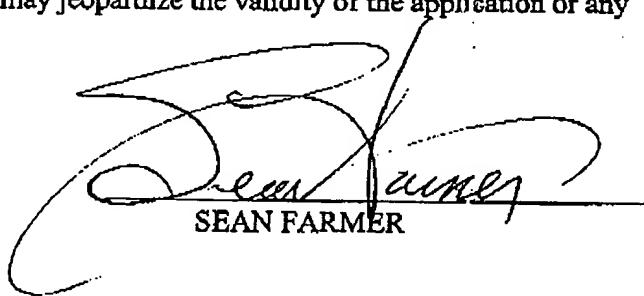
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probiotic composition does not contain any other microorganisms.

5. In clinical studies performed in California, the probiotic composition containing one billion *Bacillus coagulans* bacteria was administered to twenty-five human patients daily over a forty-five day period. Serum cholesterol levels, including total serum cholesterol, low density lipoprotein ("LDL"), very low density lipoprotein ("vLDL") and serum triglycerides, were determined for each period prior to the beginning of the treatment period and following the end of the treatment period.

6. Results of these studies demonstrate that the *Bacillus coagulans*-containing probiotic composition was surprisingly effective in reducing LDL, vLDL, serum triglycerides, and total serum cholesterol. Total serum cholesterol was, on average, reduced over 20% over the course of the studies.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



SEAN FARMER

Signed at Miami Beach, FL  
this 3 day of May 2004